## REMARKS

Claims 2, 5, 12, 14 to 19, 21, 22, and 42 are pending and under examination. Claim 3 has been canceled. Claims 2, 17, 18, 19 and 22 have been amended. Support for the amendments can be found throughout the application. No new matter has been added.

Rejection under 35 U.S.C. 112

Claim 3 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Claim 3 has been canceled, thereby obviating this rejection.

Rejection under 35 U.S.C. 103(a)

Claims 2, 3, 5, 12, and 14 to 22 were rejected under 35 U.S.C. 103(a) as allegedly obvious over Scott (U.S. Patent 6,458,287) in view of Watts (WO 98/30207) and further in view of the teachings of Unger (6,315,981), Gefter (5,968,895), Noble (US 4,574,152), Voser (US 3,725,400) and Chromecek (3,886,125). According to the Office,

> Scott does identify polysaccharides as useful macromolecules for making the delivery particles. Moreover, the teachings of each of Unger (column 16, lines 35-41) and Gefter (columns 5-6) identify carrageenan as a useful polysaccharide for making of drug delivery compositions. Thus, it would have been obvious to those skilled in the art to have used carrageenan as the macromolecule in the composition suggested in the prior art.

The claims, as amended, recite a pharmaceutical composition that includes a composition consisting of carrageenan, at least one cephalosporin entrained within or ionically bound to the carrageenan and at least one metal cation entrained within or ionically bound to the carrageenan or the cephalosporin.

None of the references cited by the Office teach or suggest that claimed composition. Scott discloses microspheres for sustained release of therapeutic agents, which require a macromolecule and at least one water soluble polymer (see Scott at col. 3, lines 27 to 30 and col. 10, lines 43 to 46). According to Scott, a macromolecule is "any molecule having a tertiary and quaternary structure or capable of having a tertiary and quaternary structure." (col. 12, lines 22 to 24). Preferred macromolecules include, e.g.,

proteins, peptides, carbohydrates, polysaccharides and nucleic acids (col. 12, lines 24 to 30). While Scott disclose that a small molecule or compound incapable of having a tertiary structure can be used in the disclosed microspheres, Scott disclose that these compounds need to be incorporated or coupled to a carrier molecule that has a tertiary or quaternary structure. Cephalosporin does not have a tertiary or quaternary structure. Thus, based upon the teachings of Scott, a skilled artisan would have expected that a composition of cephalosporin would require, at a minimum, cephalosporin, a carrier molecule and a water soluble polymer. Even if one of skill in the art were to categorize carrageenan as a polysaccharide, based upon the disclosure of Scott, one would still expect a microsphere containing cephalosporin to include an additional water soluble polymer. Further, if one of skill in the art were to categorize carrageenan as a water soluble polymer, based upon the disclosure of Scott, one would still expect a microsphere containing cephalosporin to include a carrier molecule. Therefore, Scott does not teach or suggest the claimed invention.

Turning now to the secondary references, applicants submit that none of them, i.e., Watts, Unger, Gefter, Noble, Voser or Chromecek, remedy the deficiencies of Scott. Watts describes, *inter alia*, drug compositions comprising chitosan, type A cationic gelatin, and a therapeutic agent. Unger et al. describes gas filled microparticles that further include a biocompatible lipid or polymer and a contrast agent. Gefter describe a complex of a peptide and a carrier macromolecule, preferably, carboxymethylcellulose. Noble describes ternary complexes that include cephalosporin complexed with copper (II) ions and an organic nitrogen base. Voser describes isolating cephalosporin C from solutions. Chromecek describes polymer complexes that include a polymer containing aluminum zinc or zirconium metal bound in complex form. Not one of these references provides the motivation or reasoning to include carrageenan and cephalosporin but not to include an additional polymer or carrier molecule in the microspheres described in Scott.

Accordingly, Applicants submit that no *prima facie* case of obviousness has been established and that the present rejection should be reconsidered and withdrawn.

Claims 2, 3, 5, 12, 14 to 22, and 42 were rejected as allegedly obvious over Scott in view of Watts and further in view of the teachings of Unger, Gefter, Noble, Voser and

Chromecek and further in view of Horwitz (U.S. Patent No. 5,783,561). Applicants traverse this rejection.

The deficiencies of Scott, Watts, Unger, Gefter, Noble, Voser and Chromecek were discussed above in detail. Horwitz does not remedy the deficiencies of these references. Horwitz describes, *inter alia*, treating gram positive bacterial infections using bactericidal/permeability-increasing (BPI) protein products. Horwitz would not have provided skilled practitioners with any motivation or reason to modify Scott in the way the Office proposes, and apparently Horwitz is not relied upon by the Office for such a teaching. Thus, the combination of Scott, Watts, Horwitz, Noble, Voser and Chromecek do not support a *prima facie* case of obviousness and the rejection should be withdrawn.

## CONCLUSION

Applicants ask that the proposed amendments be entered and that all rejections and objections be reconsidered and withdrawn. Please apply any other charges or credits to Deposit Account No. 50/2762, referencing Attorney Docket No. C2080-700130.

Respectfully submitted,

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Date: November 26, 2008